

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference pc-21017809		FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2004/001979	International filing date (day/month/year) 22-12-2004	Priority date (day/month/year) 22-12-2003	
International Patent Classification (IPC) or national classification and IPC See Supplemental Box			
Applicant Astra Tech AB et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 24-10-2005	Date of completion of this report 07-04-2006
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Form PCT/IPEA/409 (cover sheet) (April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001979

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

International patent classification (IPC)

A61L 29/14 (2006.01)

A61M 25/00 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001979

Box No. I Basis of the report

1. With regard to the language, this report is based on:



the international application in the language in which it was filed



a translation of the international application into _____
which is the language of a translation furnished for the purposes of:



international search (Rules 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:



the international application as originally filed/furnished



the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing *(specify)*: _____



any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing *(specify)*: _____



any table(s) related to the sequence listing *(specify)*: _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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AP3 Rec'd PCT/PTO 22 JUN 2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2004/001979

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-35</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	<u>1-35</u>	YES
	Claims	_____	NO
Industrial applicability (IA)	Claims	<u>1-35</u>	YES
	Claims	_____	NO

2. Citations and explanations (Rule 70.7)

The claimed invention

The claimed invention relates to the problem concerning providing low-friction properties to outer surfaces of catheters.

The problem is solved by using very high concentration of osmolality-increasing compound for the wetting fluid. It is especially stated that the concentration of osmolality-increasing compound should be in the line with the normal saline concentration in urine and should exceed 600 mOsm/dm³.

Prior art

In the International Search Report the following documents were cited:

D1: WO 0 047 494

D2: Spinal Cord, vol 35, no 3, 1997, Waller et al: "The importance of osmolality in hydrophilic urethral catheters: a crossover study"

D3: Spinal Cord, vol 38, 2000, Lundgren et al: "The importance of osmolality for intermittent catheterization of the urethra"

D4: WO 9 416 747

D5: WO 9 858 989

D6: Invest Radiol. 1988-09-23, Slovak et al: "Current contrast media and ioxilan comparative evaluation of vascular pain by aversion conditioning"

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

D1 describes a urethral catheter having a coated surface which exhibits reduced friction when wetted with a wetting liquid. It is in D1 stated that the wetting liquid may contain an osmolality-increasing agent such as sodium chloride. (See abstract and claims 19-20.)

D2 describes risks of urethral trauma after catheterisation with urethral catheters. It is studied how osmolality in the outer layer of the catheters effects the level of friction and the risk of trauma. In D2 the conclusion is made that the osmolality of the outer layer of a hydrophilic catheter should equalise the osmolality of human urine to cause minimum trauma. This is in one of the studied catheters done by in the outer layer adding sodium chloride that, when soaked in water, increases the osmolality to 800 mOsm/kg, as in human urine. The osmolality values measured for the catheters in D2 are in the interval 800-1150 mOsm/kg. (See the whole article. Especially abstract; page 230, left column, line 2-54; page 231, right column, line 7-19; page 232, right column, line 6-27.)

Documents D3-D6 represent the prior art. The claimed invention is not considered to be anticipated by these documents.

Statement of reason

The cited documents represent the general state of the art. The invention defined in claims 1-35 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed catheter assembly having a wetting fluid comprising an osmolality-increasing compound concentration exceeding 600 mOsm/dm³, wherein this osmolality-increasing concentration improves stability and water retention of the catheter.

Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-35 is novel and is considered to involve an inventive step. The invention is industrially applicable.